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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
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<i>This Document Relates to:</i>	:	<b>ANSWER AND AFFIRMATIVE</b>
Jo Anne Brimer	:	<b>DEFENSES OF MERCK</b>
v. Merck & Co., Inc.	:	<b>&amp; CO., INC.;</b>
Case No: 1: 07-cv-6850-JFK	:	<b>DEMAND FOR JURY TRIAL</b>
	:	
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Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**PARTIES**

1. Merck is without knowledge or information sufficient to form a belief as to the allegations of the first two sentences of Paragraph 1. Merck denies each and every allegation of the third sentence of Paragraph 1, except admits that Plaintiff has filed this action seeking damages, but denies that there is any legal or factual basis for same.

2. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 2.

3. Merck admits that it is registered to do business in the State of Louisiana.

4. Merck is without knowledge as to what is meant by the phrase “regularly transacted,” so the allegations in Paragraph 4 are denied.

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 5 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

6. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 6 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 6.

7. Merck is without knowledge as to what is meant by the phrase “substantial revenue” so the allegations in Paragraph 7 are denied.

8. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 8 are denied.

#### **JURISDICTION AND VENUE**

9. The allegations of Paragraph 9 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 9.

10. The allegations of Paragraph 10 are conclusions of law to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 10.

**FACTUAL ALLEGATIONS**

11. Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information and admits that Plaintiff purports to bring this action to recover damages and/or equitable relief, but denies there is any factual or legal basis for same. Except as expressly admitted herein, Merck denies the allegations of Paragraph 11, except Merck states that it is without knowledge as to whether Plaintiff ingested and/or was prescribed FOSAMAX®.

12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 12. Merck denies each and every allegation of the second sentence of Paragraph 12.

13. Merck denies each and every allegation in Paragraph 13, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

14. Merck denies each and every allegation in Paragraph 14, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 14 inconsistent with that prescribing information.

15. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 15 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 15 with respect to Aredia and Zometa inconsistent with that prescribing information.

16. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 16 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 16 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations in Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation in Paragraph 25, except that Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but respectfully refers the Court to said document for its actual language and full text.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29, except that Merck admits that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.

30. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies all remaining allegations of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 32.

33. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

**COUNT I -- NEGLIGENCE**

41. Merck repleads its answers to Paragraphs 1 through and including 40, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

42. Merck denies each and every allegation of Paragraph 42.

43. The allegations in Paragraph 43 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

44. Merck denies each and every allegation of Paragraph 44, including each and every allegation of subparts (a) through (f).

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

**COUNT II – STRICT LIABILITY**

49. Merck repleads its answers to Paragraphs 1 through and including 48, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

50. Merck denies each and every allegation of Paragraph 50, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine

FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to whether Plaintiff ingested FOSAMAX®.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52, except that Merck states that it is without knowledge as to the manner in which Plaintiff used FOSAMAX®.

53. Merck denies each and every allegation of Paragraph 3 except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she ingested.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. The allegations of the first sentence of Paragraph 56 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules. Merck denies each and every allegation of the second sentence of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

**COUNT III – MISREPRESENTATION AND SUPPRESSION OF SAFETY  
INFORMATION BY DEFENDANT**

61. Merck repleads its answers to Paragraphs 1 through and including 60, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63, including each and every allegation of subparts (a) and (b).

40.<sup>1</sup> Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. The allegations in Paragraph 51 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

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<sup>1</sup> Plaintiff's paragraphs are mis-numbered. Thus, paragraph numbers 40 – 63 are repeated.



52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

**COUNT IV – REDHIBITION**

55. Merck repleads its answers to Paragraphs 1 through and including 54, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

56. Merck denies each and every allegation of Paragraph 56, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

**COUNT V – CLAIM UNDER THE LOUISIANA PRODUCTS LIABILITY ACT:  
L.A.R.S. 9:2800.56**

63. Merck repleads its answers to Paragraphs 1 through and including 62, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

64. The allegations of Paragraph 64 are conclusions of law to which no response is required. To the extent a response is required, Merck respectfully refers the Court to the identified section of the code for its actual language and full text.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

**COUNT VI – CLAIM UNDER THE LOUISIANA PRODUCTS LIABILITY ACT:**  
**LA.R.S. 9:2800:57**

69. Merck repleads its answers to Paragraphs 1 through and including 68 and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

**COUNT VII – CLAIM UNDER THE LOUISIANA PRODUCTS LIABILITY:**  
**LA.R.S. 9:2800.58**

75. Merck repleads its answers to Paragraphs 1 through and including 74, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

**COUNT VIII – EXPRESS BEACH OF WARRANTY**

80. Merck repleads its answers to Paragraphs 1 through and including 79, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

81. Merck denies each and every allegation of Paragraph 81, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

82. Merck denies each and every allegation of Paragraph 82, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

83. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 83. Merck denies each and every allegation of the second sentence of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

**COUNT VIII – BREACH OF IMPLIED WARRANTY**

86. Merck repleads its answers to Paragraphs 1 through and including 85, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

87. Merck denies each and every allegation of Paragraph 87, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

88. Merck denies each and every allegation of Paragraph 88, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 92.

93. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

**COUNT IX – UNJUST ENRICHMENT**

96. Merck repleads its answers to Paragraphs 1 through and including 95, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

97. Merck denies each and every allegation of Paragraph 97.

**COUNT X – ACTUAL AND CONSTRUCTIVE FRAUD**

98. Merck repleads its answers to Paragraphs 1 through and including 97, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**PRAYER FOR RELIEF**

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

#### **FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

#### **SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

#### **THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully

assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.



**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because,

among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Louisiana Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's

claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claimed are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims of fraud are not pleaded with the required particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

The substantive law of Louisiana applies to Plaintiff's claim.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims against Merck based on theories of liability or elements of damages provided in the Louisiana Products Liability Act, Plaintiffs have failed to allege facts that would overcome the defenses available under the Louisiana Products Liability Act. La. Rev. Stat. § 9:2800.59(A).

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Merck specifically denies that FOSAMAX®, or any product manufactured by Merck, was the cause of any harm to Plaintiff or that any Merck product was unreasonably dangerous under Louisiana law. Merck further would show that Plaintiff's sole and exclusive cause and right of action against Merck for alleged damages relating to a product manufactured by Merck arises under the Louisiana Products Liability Act, La. Rev. Stat. 2800.52, *et seq.*, and that Plaintiff has no cause or right of action against Merck under any other theory of liability, including but not limited to, negligence, strict liability, breach of warranty, fraudulent misrepresentation, fraudulent concealment, and/or punitive damages, as alleged in Plaintiff's Complaint.

**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Merck adopts and incorporates herein by reference all affirmative defenses set forth in the Louisiana Products Liability Act, La. Rev. Stat. 9:2800:52, *et seq.*, not otherwise specifically set forth herein.

**FORTY-NINTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims against Merck based on theories of liability not provided for in the Louisiana Products Liability Act, those claims are barred. La. Rev. Stat. § 9:2800.51, *et seq.*

**FIFTIETH AFFIRMATIVE DEFENSE**

Plaintiff fails to state a claim upon which relief can be granted for medical monitoring or compensation for medical monitoring.

**FIFTY-FIRST AFFIRMATIVE DEFENSE**

Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**FIFTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff is not entitled to recover exemplary or punitive damages because the standards and procedures for determining and reviewing such awards under the applicable law do not sufficiently ensure a meaningful individualized assessment of appropriate deterrence and retribution.

**FIFTY-THIRD AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages without proof of every element beyond a reasonable doubt would violate Merck's rights under the applicable state and federal constitutions.

**FIFTY-FOURTH AFFIRMATIVE DEFENSE**

Unless Merck's liability for punitive damages and the appropriate amount of punitive damages are each required to be established by clear and convincing evidence, any awards of punitive damages would violate Merck's due process rights guaranteed by the applicable state and federal constitutions.

**FIFTY-FIFTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because any award of punitive damages without bifurcating the trial as to all punitive damages issues would violate Merck's due process rights guaranteed by the applicable state and federal constitutions.

**FIFTY-SIXTH AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages subject to no pre-determined limit, either a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose would violate Merck's due process rights guaranteed by the applicable state and federal constitutions.

**FIFTY-SEVENTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages for the purpose of compensating Plaintiff for elements of damages not otherwise recognized by the applicable state law would violate Merck's due process rights guaranteed by the applicable state and federal constitutions.



**FIFTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff should not be afforded the right to a jury trial on her claim for punitive damages.

**FIFTY-NINTH AFFIRMATIVE DEFENSE**

To the extent Plaintiff has settled or will settle in the future with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**SIXTIETH AFFIRMATIVE DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

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Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck hereby demands a trial by jury on all of Plaintiffs' claims.

DATED: New York, New York  
August 15, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/  
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